

Transforming Clinical Pathways

Adil I. Khan, MSc, PhD

The coronavirus disease 2019 (COVID-19) pandemic highlighted the importance of point-of-care testing (POCT)—tests done near the patient to provide fast, actionable results to improve patient management. This pandemic demonstrated, more so to the public at large, the value of having a process in place that would allow the efficient triaging of patients to reduce virus spread and contain the disease, as well as aiding in its management in the intensive care isolation units with point-of-care blood gas instruments. The huge loss in life at a global scale caused the US Food and Drug Administration to issue an Emergency Use Authorization announcement that allowed partially validated COVID-19 diagnostics tests to be released into the market by the manufacturer, leaving the onus of full validation on the laboratory. Point-of-care tests are designed so that they are simple to use and require either no or very little maintenance. However, this simplicity is also their Achilles heel, and, without rigorous quality assurance processes in place, they have the potential to cause inaccurate results and patient mismanagement.

This special section in the *Archives of Pathology & Laboratory Medicine* focuses on POCT and is split into multiple issues. Part I is a collection of 6 articles that cover diverse and topical areas in POCT.

In the first article, Gerald J. Kost, MD, PhD, MS, discusses how POCT can be leveraged in epidemics and pandemics to minimize societal and economic harm, using COVID-19 and Ebola virus disease as examples; in addition, he reviews barriers to implementation and puts forward potential resolutions. Health care inequity is a global concern; Samarina M. A. Musaad, MB BS, MPH, explains how POCT, because of its very nature and design concept, can help reduce this inequity gap. Nadia Ayala-Lopez, MLS(ASCP), PhD, and James H. Nichols, PhD, review the merits as well as the risks of direct-to-consumer testing, an area that is rapidly increasing because of consumer interest in monitoring and tracking health. Kidney disease is a major problem in rural Australia, particularly among the indigenous population. As a result, urine albumin to creatinine

ratio is often measured at the point-of-care in a network of clinics. Because of limited data on the quality of this test, Tamika Regnier, BMedSc, and colleagues investigate this aspect using 16 years of analytical quality data. Mark Inman, MD, and colleagues assess using glucose meters and the clinical significance of hematocrit interference on blood glucose results used for insulin dosing, an important area in the critically ill and inpatient diabetic population. Point-of-care blood gas instruments are not commonly used in the nephrology department. However, Ana Laila Qasem Moreno, MD, and colleagues discuss the clinical, operative, and economic outcomes of placing them there as opposed to the central laboratory.

Articles covering other aspects of POCT as well as their use in different settings will follow in subsequent issues of the *ARCHIVES*. With the US opioid epidemic as the backdrop, Zhao Li, PhD, and Ping Wang, PhD, review the current drugs of abuse POCTs available on the market, their challenges, and the opportunities provided for research and development. Although diagnostic tests are available for Zika virus, the reverse transcription polymerase chain reaction gold standard requires considerable technical expertise. Sandhya Sharma, MS, Md Alamgir Kabir, MS, and Waseem Asghar, PhD, demonstrate an easy-to-perform, fully automated lab-on-a-chip Zika virus POCT that uses loop mediated isothermal amplification to give a result within 40 minutes. In an effort to combat antimicrobial resistance to antibiotics, Paul C. Adamson, MD, MPH, and colleagues provide a comprehensive review of POCT for sexually transmitted infections so that more targeted therapy can be delivered.

Anna K. Füzéry, BSc, PhD, and Dr Kost, review POCT practices in an Alberta emergency medical service, discussing potential areas where lapses could cause patient mismanagement and risk mitigation strategies. Mark Shephard, BSc (Hons), MSc, PhD, and colleagues, using rural and remote primary care settings in Australia, lay the groundwork for anyone wanting to establish a POCT service in a resource-limited setting. They also discuss the benefits and limitations in Australia, and these concepts can be broadly applied to other countries. Point-of-care testing as practiced in rural New Zealand is presented by Geoffrey C. E. Herd, MAppSci, with Dr Samarina M. A. Musaad. They discuss the various POCT initiatives introduced by local health authorities to improve clinical outcomes of chronic diseases and lessons that can be learned.

Point-of-care testing in remote areas is feasible only if there is good analytical quality and delivery of service and if results have some clinical utility so that they improve patient management. Susan Janet Matthews, PhD, and colleagues clearly demonstrate this in their example with quality

Accepted for publication June 26, 2020.

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The author has no relevant financial interest in the products or companies described in this article.

doi: 10.5858/arpa.2020-0438-ED

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indicators that are transferable to other geographical locations. Antimicrobial resistance has always been a global concern, and more so in COVID-19 coinfections. Dr Kost discusses point-of-care technology solutions available and initiatives for research and development. In a subsequent article titled “Designing and Interpreting COVID-19 Diagnostics—Mathematics, Visual Logistics, and Low Prevalence,” Dr Kost describes the importance of factors such as prevalence on performance metrics for COVID-19 diagnostic tests and how healthcare workers can use free software available on the internet to perform their own analysis. Studies have shown that delayed detection of acute kidney injury is associated with poor outcomes in trauma and burn patients. Hooman H. Rashidi, MD, and colleagues investi-

gate how artificial intelligence can enhance the predictive performance of acute kidney injury biomarkers in trauma and burn patients. POCT is commonly used to improve patient management. David Alter, MD, evaluates the quantity and quality of the available literature to determine the validity of this viewpoint. Hyung-Doo Park, MD, PhD, gives an overview of the point-of-care technologies available in diagnostic hematology, clinical chemistry, and clinical microbiology that are enabling physicians to make effective decisions to help patient disease management.

Point-of-care testing is one of the fastest growing segments of laboratory medicine and is transforming clinical pathways. With that said, I hope you will enjoy reading these collections of articles in this special section.



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Adil I. Khan, MSc, PhD, is an associate professor of pathology at the Lewis Katz School of Medicine, Temple University, in Philadelphia, Pennsylvania, and the medical director for point-of-care testing and clinical chemistry for the Temple University Health System. He completed his MSc in the United Kingdom in immunology of infectious diseases at the London School of Hygiene & Tropical Medicine (1992) and his PhD in immunology from the Hammersmith Hospital Campus of the National Heart & Lung Institute, Imperial College London (2000). Dr Khan then pursued a postdoctoral research fellowship at the University of Calgary, Canada, studying the role of L-selectin and CD44 in models of acute inflammation, followed by a postdoctoral clinical chemistry training fellowship at the University of Texas Southwestern Medical Center at Dallas. Since 2006, he has been teaching at Temple University, lecturing to pathology residents, medical students, and students of podiatric medicine. Dr Khan’s research interests include understanding the role of adhesion molecules and extracellular vesicles in inflammation and identifying novel markers of inflammation. On the clinical side, as well as providing expert consultation to his colleagues, his interest is in clinical trials of point-of-care testing devices/laboratory instruments and assay development. He is a national and international speaker, has numerous publications and book chapters, has coauthored various laboratory guidelines for the Clinical Laboratory Standards Institute, and has organized workshops and symposia. He has also been the treasurer and past chair of the Philadelphia section of the American Association of Clinical Chemistry and is currently the chair of the International Federation of Clinical Chemistry and Laboratory Medicine Executive Board Committee on Point-of-Care Testing.